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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,376	07/01/2003	John S. Patton	0005.15	3703

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NEKTAR THERAPEUTICS
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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,376	PATTON ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *26-30 and 35-38* is/are allowed.

6)☒ Claim(s) *31-34 and 39-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4-18-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The RCE dated 4-18-06 is acknowledged.

Claims included in the prosecution are 26-43.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 31-34 and 39-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-58 of copending Application No. 10/245,705. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 28 in the copending application are drawn to generic pharmaceutical agent in an amorphous dry powder form having the particle sizes of less than 10 microns and claims 32 and 33 identify insulin as one of the pharmaceutical agents. Claim 41 further identifies the composition

is a spray dried composition; instant claims drawn specifically to insulin and in specific amounts therefore, are anticipated by the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 31-34 and 39-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-43 of copending Application No. 10/245,706. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to insulin composition in a carrier buffer in a powder form suitable for administration by inhalation. The dependent claim 32 identifies the particle sizes to be less than 10 microns. The dependent claim 28 identifies the buffer to be trehalose, lactose and other sugars. Instant claims are drawn to powdered amorphous insulin compositions with particle sizes below 10 microns and with moisture content of below 10 % containing the same carbohydrate material. The claims in the copending application thus, are generic with respect to the amounts of insulin and the particle sizes and therefore, instant claims are anticipated by the claims in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 31-34 and 39-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of U.S. Patent No. 6,358,530. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in said patent are drawn to generic

polypeptide active agent and instantly claimed insulin is a polypeptide and therefore, anticipated by the patented claims. In the patented claims, one of the excipients claims is a carbohydrate and the dependent claim 5 identifies the carbohydrate to be lactose, trehalose and others just as in instant claims. The patented claims are generic with respect to the amount of the polypeptide and instant amounts of insulin are therefore, anticipated by the patented claims. The patented claims do not exclude the presence of buffers such as sodium citrate in instant claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 31-33 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz (5,354,562) of record.

Platz while teaching particles containing insulin and other polypeptide drugs is suggestive of the use of mannitol, and trehalose along with insulin; the particle sizes are between 0.5 to 4 microns (note the abstract and column 2, line 22 through col. 4, line 42). Although in Examples, Platz uses amounts, which are closer to the claimed lower range, on col. 4, lines 42-45, Platz teaches that the milled powder can be formulated neat or with the bulking agents and when the bulking agents are used, they will normally

constitute about 50 to 99.9 % of the formulation. Therefore it would have been obvious to one of ordinary skill in the art, to choose the desired amount of insulin and the bulking agents since the amount of insulin depends upon the severity of the diabetes in the patient.

7. Claims 34 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz (5,354,562) in view of Chien (5,042,975), or Markussen (4,946,828), or Hansen (4,614,730) or JP 56 138 110, or JP 56 138 111 by themselves or in combination (all are of record).

Platz has been discussed above. The reference of Platz does not teach the use of citrate as the buffer for insulin. Such a use however, would have been obvious to one of ordinary skill in the art since Chien and Markussen, Hansen and JP 110, JP 111 each teach that these salts are commonly used in combination with insulin and an artisan would expect similar results (note the examples in Chien and Markussen; col. 4, lines 49-54 in Hansen; abstract in JP). One of ordinary skill in the art would be motivated further to use citrate buffers in insulin preparations since JP 56 138 111 teaches that the absorption of insulin is improved by this buffer (note the abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK